UNITED STATES DISTRICT COURT
DISTRICT OF RHODE ISLAND

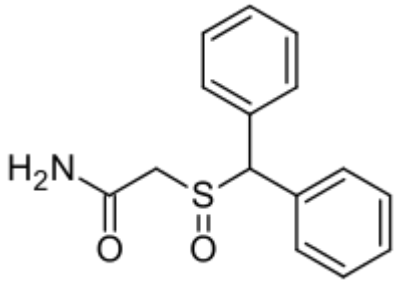
CITY OF PROVIDENCE, RHODE ISLAND, Plaintiff, v. CEPHALON, INC., BARR PHARMACEUTICALS, INC., MYLAN LABORATORIES, INC., MYLAN PHARMACEUTICALS, INC., RANBAXY LABORATORIES, LTD., RANBAXY PHARMACEUTICALS, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD., and TEVA PHARMACEUTICALS USA, INC., Defendants.	Civil Action No. _____

The City of Providence, Rhode Island ("Plaintiff" or "Providence") files this Complaint against Defendants Cephalon, Inc. ("Cephalon"), Barr Pharmaceuticals, Inc. ("Barr"), Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"), Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy"), and Teva Pharmaceuticals Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"). The following allegations are based upon the investigation of counsel and information and belief as follows:

I. NATURE OF THE ACTION

1. This is an antitrust action seeking treble damages arising out of Defendants' scheme to unlawfully delay generic competition in the market for the prescription drug Provigil. Provigil is a drug used to treat wakefulness disorders such as narcolepsy, shift work sleep disorder, and excessive daytime sleepiness associated with obstructive sleep apnea.

2. The active pharmaceutical ingredient in Provigil is modafinil with a chemical formula of $C_{15}H_{15}NO_2S$, represented graphically below:



3. Plaintiff brings this action as an indirect purchaser who purchased, paid, and/or provided reimbursement for branded Provigil and/or its generic equivalent, modafinil, from June 1, 2006 – September 30, 2013.

4. Defendants employed an unlawful scheme designed to prevent or delay a less expensive generic version of Provigil from entering the market. The scheme included misrepresentations to the U.S. Patent and Trademark Office ("PTO"), sham patent infringement litigation, and reverse settlement payments in that litigation by Cephalon to makers of generic modafinil (Defendants Barr, Mylan, Ranbaxy, and Teva, collectively "Generic Defendants"), as further described herein, in return for keeping generic modafinil off the market from June 1, 2006 – September 30, 2013. Barr was acquired by Teva in 2008. Cephalon was acquired by Teva in 2011.

5. As a result of its unlawful scheme to keep generic versions of Provigil off the market, and in violation of California, Florida, Illinois, Massachusetts, Maine, and Rhode Island antitrust and consumer protection laws, Defendant Cephalon: (i) illegally maintained monopoly power in the market for modafinil in the United States from 2006 to 2011 or 2012, and sold more

than $4 billion of Provigil during that time; (ii) maintained the price of modafinil at supra-competitive levels; and (iii) overcharged Plaintiff hundreds of thousands of dollars by depriving it of the benefits of unrestricted competition and access to less expensive generic versions of modafinil.

6. Cephalon marketed and sold Provigil in California, Florida, Illinois, Massachusetts, Maine, and Rhode Island.

7. As a result of Defendants' unlawful conduct, Plaintiff paid higher prices for modafinil when substantially lower prices would have been available but for Defendants' unlawful conduct.

8. As a direct and proximate result, Plaintiff was injured in its business or property.

II. PARTIES

Plaintiff

9. Plaintiff City of Providence, Rhode Island ("Providence") is a municipal corporation with a principal address of 25 Dorrance Street, Providence, Rhode Island. Providence is a self-insured health and welfare plan, which purchases, pays, and/or provides reimbursement to its employees (and/or plan beneficiaries) for some or all of the purchases of prescription drugs including Provigil and its generic equivalent, modafinil. Providence indirectly purchased, paid, and/or provided reimbursement for some or all of the purchase price of the prescription drug Provigil and its generic equivalent, modafinil for people who reside in California, Florida, Illinois, Massachusetts, Maine, and Rhode Island. As a direct and proximate result of Defendants' anticompetitive conduct, Providence paid more for modafinil than it would have absent Defendants' unlawful anticompetitive conduct.

Defendants

10. Cephalon, Inc. was a biopharmaceutical company that developed, manufactured, and marketed pharmaceuticals and related products in the United States. Cephalon had been incorporated under the laws of the State of Delaware, with its principal place of business at 41 Moores Road, Frazer, PA 19355. On May 2, 2011, Teva announced its acquisition of Cephalon. Today, Cephalon exists as a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd. that manufactures, markets, and/or distributes more than nine drugs in the United States, including Provigil.

11. Barr Pharmaceuticals, Inc. (formerly known as Barr Laboratories, Inc.) is a generic drug manufacturer incorporated under the laws of the State of Delaware, with its principal place of business at Two Quaker Road, Pomona, New York 10970. Barr develops, manufactures, and markets generic versions of brand name drugs. On July 18, 2008, it was announced that Teva Pharmaceutical Industries, Ltd. would acquire Barr Pharmaceuticals, Inc. for $7.46 billion plus the assumption of net debt of approximately $1.5 billion. Today, Barr Pharmaceuticals exists only as a sub-division of Teva Pharmaceuticals, as part of the Teva Active Pharmaceutical Ingredients (TAPI) division.

12. Mylan Laboratories, Inc. is incorporated under the laws of the Commonwealth of Pennsylvania, with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Mylan's subsidiary, Mylan Pharmaceuticals, Inc., is located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Mylan principally develops, manufactures, and markets generic versions of brand name drugs.

13. Ranbaxy Laboratories, Ltd. is a generic drug manufacturer organized under the laws of India, and Ranbaxy Pharmaceuticals, Inc., a wholly owned subsidiary, has its

principal place of business at 600 College Road East, Suite 2108, Princeton, New Jersey 08540.

14. Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Teva Pharmaceutical Industries, Ltd., an Israeli company. Teva Pharmaceuticals USA, Inc. is incorporated under the laws of the State of Delaware, having its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454. Teva principally develops, manufactures, and markets generic versions of brand name drugs. Teva acquired Cephalon, Inc. and Barr Laboratories, Inc. in 2011 and 2008, respectively.

III. JURISDICTION AND VENUE

15. The Court has jurisdiction over this matter under 28 U.S.C. § 1332(a) as the amount in controversy exceeds $75,000.00 and involves diversity of citizenship. The Court has supplemental jurisdiction over Plaintiff's pendent state law claims pursuant to 28 U.S.C. § 1367.

16. Venue is appropriate in this district under 28 U.S.C. § 1391 because Defendants transact business within this district, and a substantial part of the interstate trade and commerce involved and affected by the violations of the antitrust laws was and is carried on in part within this district. The acts complained of have and will continue to have substantial effects in this district.

IV. REGULATORY FRAMEWORK

A. NDA Approval and the Hatch-Waxman Act

17. Under the federal Food, Drug, and Cosmetics Act ("FDC Act"), 21 U.S.C. §§ 301-392, a manufacturer who creates a new, pioneer drug must obtain the approval of the U.S. Food and Drug Administration ("FDA") to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy

of the drug, as well as any information on applicable patents.

18. Upon FDA approval of a brand-name manufacturer's NDA, it is published in the "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly referred to as the "Orange Book"). The Orange Book lists any patents: (i) that the brand-name manufacturer claims for the approved drug or its approved uses; and (ii) for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(j)(7)(A)(iii).

19. In 1984, Congress amended the FDC Act with the enactment of the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly referred to as the "Hatch-Waxman Act."

20. The Hatch-Waxman Act simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file a lengthy and costly NDA in order to obtain FDA approval. The Act provides an expedited review process by which generic manufacturers may file an Abbreviated New Drug Application ("ANDA").

21. The ANDA relies on the scientific findings of safety and efficacy included by the brand-name drug manufacturer in the original NDA. The ANDA filer, however, must scientifically demonstrate to the FDA that the generic drug it is going to market is just as safe and effective as the corresponding brand-name drug through demonstrations of bioequivalence. A demonstration of bioequivalence means that, within certain set parameters of variability, the generic product delivers the same amount of active ingredient into the patient's blood stream for the same amount of time as the corresponding brand drug. The range of acceptable variability afforded to generic drugs for demonstrating bioequivalence is the same lot-to-lot (*i.e.*, batch-to-batch) range of variability afforded to brand companies when manufacturing their own brand

drugs.

22. Generally speaking, ANDA filers that demonstrate bioequivalence seek to have their generic products deemed to be "AB-rated" to the corresponding brand-name drug, sometimes referred to as the "reference listed drug." AB-rated generics are those that have been determined by the FDA to be therapeutically equivalent (*i.e.*, bioequivalent) and pharmaceutically equivalent to their brand-name counterparts. Pharmaceutical equivalence means the generic drug and branded reference listed drug have, among other things, the same active ingredient, same strength, same route of administration, and same dosage form. Generic drugs that do not fulfill all of these requirements cannot be deemed to be AB-rated to the targeted reference listed drug.

23. FDA approval of an ANDA requires a generic manufacturer's ANDA to contain one of the following four certifications: (i) the brand-name drug has no patent associated with it (a "Paragraph I certification"); (ii) the brand-name drug's patents have expired (a "Paragraph II certification"); (iii) the brand-name drug's patents will expire before the generic enters the market (a "Paragraph III certification"); or (iv) the patent for the brand-name drug is invalid or will not be infringed by the generic product (a "Paragraph IV certification"). 21 U.S.C. § 355(j)(2)(A)(vii).

24. If a generic manufacturer files a Paragraph IV certification that the listed patent is invalid or will not be infringed, it must promptly give notice to both the NDA owner and the owner of the patent(s) at issue. The filing of an ANDA with a Paragraph IV certification gives rise to a cause of action for patent infringement. 35 U.S.C. § 271(e)(2)(A). If the patent owner initiates an infringement action against the ANDA filer within 45 days, then the FDA may not finally approve the ANDA until the earlier of either 30 months or the issuance of a decision by a

court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). If, however, the patent owner fails to initiate a patent infringement action within 45 days after receiving notice of the generic manufacturer's Paragraph IV certification, the FDA may grant final approval to the generic manufacturer's ANDA upon satisfying itself as to the safety and efficacy of the generic product. Accordingly, the timely filing of an infringement action provides the patent owner with the equivalent of a 30-month automatic preliminary injunction. Prompt disposition of such an action, as through a motion for summary judgment, may mean more rapid approval for a generic manufacturer subject to such a stay.

25. To encourage generic manufacturers to challenge branded drug patents and/or to design around them, the Hatch-Waxman Act grants the first Paragraph IV ANDA filer(s) a 180-day exclusivity period to market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand-name drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. § 355(j)(5)(D).

26. Typically, AB-rated generic versions of brand-name drugs are priced significantly below the brand-name counterparts. Because of the price differentials, and other institutional features of the pharmaceutical market, AB-rated generic versions are rapidly and substantially substituted for their brand-name counterparts. When multiple generic manufacturers enter the market, prices for generic versions of a drug predictably decrease significantly because of competition among the generic manufacturers, and because the loss of sales volume by the brand-name drug to the corresponding generics is dramatic.

27. An AB rating is particularly significant to a generic manufacturer because, under the statutory regime enacted by Congress (*i.e.*, the Hatch-Waxman Act) and most state legislatures (*i.e.*, Drug Product Selection laws, or "DPS laws"), pharmacists may (and, in most

states, must) substitute an AB-rated generic version of a drug for the brand-name drug without seeking or obtaining permission from the prescribing doctor. Indeed, both Congress and state legislatures have actively encouraged generic substitution because of their recognition that the economics of the pharmaceutical industry prevent generic manufacturers from simultaneously: (i) engaging in the type of heavy promotion or "detailing" typically done by brand-name manufacturers; and (ii) providing the enormous cost savings to purchasers and consumers generated by generic drugs.

28. Generic competition enables Plaintiff to: (i) purchase generic versions of brand-name drugs at substantially lower prices; and/or (ii) purchase the brand-name drug at reduced prices. However, until generic manufacturers enter the market with an AB-rated generic, there is no bioequivalent generic drug that competes with the brand-name drug and, therefore, the brand-name manufacturer can continue to charge supra-competitive prices profitably. Consequently, brand-name drug manufacturers have a strong incentive to use various anticompetitive schemes, including the tactics alleged herein, to delay the introduction of AB-rated generic competition into the market.

B. AB-rated Generic Versions of Brand-Name Drugs Are Significantly Less Expensive, and Take Significant Sales Directly from the Corresponding Brand-Name Versions

29. Competition from lower-priced AB-rated generic drugs saves American consumers $8 to $10 billion a year. As set forth *infra*, however, these consumer savings mean lower profits for brand name drug companies. It is well-established that when AB-rated generic entry occurs, the brand name drug company suffers a rapid and steep decline in sales and profits on its reference listed drug.

30. Since passage of the Hatch-Waxman Act, every state has adopted substitution

laws that either require or permit pharmacies to substitute AB-rated generic equivalents for branded prescriptions (unless the prescribing physician has specifically ordered otherwise).

31. The threat of AB-rated generic competition thus creates a powerful incentive for brand companies to protect their revenue streams. This incentive can prompt brand companies to create innovative new products or new versions of old products that offer no real medical benefits to patients. It may also drive brand companies to seek to obstruct generic drug competition by engineering unlawful, anticompetitive schemes to delay or prevent less expensive generic equivalents from entering the market, including by entering into unlawful agreements, intended to interfere with the normal brand-to-generic competition contemplated and encouraged by the Hatch-Waxman Act and various state laws.

32. Such tactics can be an effective, *albeit* anticompetitive, way to "game the regulatory structure" that governs the approval and sale of generic drugs, thereby frustrating the intention of federal and state law designed to promote and facilitate price competition in pharmaceutical markets.

C. The Hatch-Waxman Amendments

33. The Hatch-Waxman Amendments, enacted in 1984, simplified the regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984). A manufacturer seeking approval to sell a generic version of a brand drug may instead file an ANDA. An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's original NDA, and must further show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the

brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

34. The FDCA and Hatch-Waxman Amendments operate on the proven scientific principle that bioequivalent drug products containing identical amounts of the same active ingredients, having the same route of administration and dosage form, and meeting applicable standards of strength, quality, purity, and identity, are therapeutically equivalent and may be substituted for one another. Bioequivalence demonstrates that the active ingredient of the proposed generic drug would be present in the blood of a patient to the same relative extent and for the same amount of time as the brand counterpart. 21 U.S.C. § 355G)(8)(B).

35. Congress enacted the Hatch-Waxman Amendments to expedite the entry of less-expensive generic competitors to brand drugs, thereby reducing healthcare expenses nationwide. Congress also sought to protect pharmaceutical manufacturers' incentives to create new and innovative products.

36. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand manufacturers. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion; by 2013, total prescription drug revenue had climbed to more than $329.2 billion, with generic drugs accounting for 86% of prescriptions.[1] Generics are now dispensed 95% of the time when a

[1] See IMS INSTITUTE FOR HEALTHCARE INFORMATICS, MEDICINE USE AND SHIFTING COSTS OF HEALTHCARE, at 30, 51 (Apr. 2014), *available at*

generic form is available.[2]

D. ANDA Paragraph IV Certification

37. If a generic manufacturer files a Paragraph IV certification, it must notify the brand manufacturer, and the brand manufacturer can delay FDA approval of the ANDA simply by suing the ANDA applicant for patent infringement. If the brand manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification, the FDA will not grant final approval to the ANDA until the earlier of: (i) the passage of 30 months from the date of receipt of the Paragraph IV notice; or (ii) the issuance of a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). Until one of those conditions occurs, the FDA may grant "tentative approval," but cannot authorize the generic manufacturer to market its product (*i.e.*, grant final approval). The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

First-filer's 180-day exclusivity period

38. Generics may be classified as: (i) first-filer generics; (ii) later generic filers; and (iii) the brand's own authorized generic.

39. To encourage manufacturers to seek approval of generic versions of brand drugs, the Hatch-Waxman Amendments grant the first generic manufacturer who files an ANDA with a Paragraph IV certification (the "first-filer") a 180-day period to exclusively market the generic version of the drug, during which the FDA may not grant final approval to any other generic manufacturer's ANDA for the same brand drug. 21 U.S.C. § 355(j)(5)(B)(iv) and 21 U.S.C. §

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http://www.imshealth.com/cds/imshealth/Global/Content/Corporate!IMS%20Health%201nstitute/Reports/Secure!II HI_US_Use_of_Meds_for_2013. pdf (last accessed June 6, 2014); *Id*. at 51.

[2] *Id.* at 51.

355(j)(5)(D). Two or more companies can be first-filers if they file first on the same day.

40. The Supreme Court has recognized that "this 180-day period of exclusivity can prove valuable, possibly worth several hundred million dollars" to the first filer.[3]

41. A first-filer that informs the FDA that it intends to wait until all Orange Book listed patents expire before marketing its product does not qualify for a 180-day exclusivity period. Congress created this 180-day period to incentivize generic manufacturers to challenge weak or invalid patents, or to invent around such patents by creating non-infringing generics.

E. Brand and Generic Companies Have Strong Financial Incentives to Agree to Anticompetitive Terms

42. An anticompetitive agreement entered into between the brand and first-filer generic often subjects later ANDA filers to the delayed entry date agreed to between the brand manufacturer and its conspiring first-filer generic.

43. In the absence of an anticompetitive agreement between the brand company and the first-filers, the later ANDA filers have pro-competitive incentives. They are motivated to expend resources to challenge the brand company's patent (knowing that the first-filer generic is also fighting a patent infringement suit) and to enter the market as early as possible.

44. Thus, some later generics decide to simply give in to, or even join, the conspiracy between the brand company and the first-filer generics by dropping their challenges to the brand's patents and staying off the market until after entry by the first-filers.

45. Such agreements are fundamentally anticompetitive and are contrary to the goals of the Hatch-Waxman statutory scheme. In particular, they extend the brand manufacturer's monopoly profits by blocking access to more affordable generic drugs, forcing purchasers to buy the expensive brand instead.

[3] *FTC v. Actavis, Inc.*, 570 U.S. ___, 133 S. Ct. 2223, 2229 (2013).

46. The unlawful agreements brokered by Cephalon with each Generic Defendant, and continuously performed by all defendants from their date of execution, have resulted in many years of unlawful monopolization in the market for Provigil and its AB-rated generic equivalents.

V. DEFENDANTS' ANTICOMPETITIVE CONDUCT

47. Cephalon began selling Provigil shortly after its NDA received FDA approval on December 24, 1998. Provigil's five years of new chemical entity ("NCE") exclusivity expired on December 24, 2003.

48. Cephalon also received Orphan Drug exclusivity by representing that modafinil was a drug used to treat a rare disorder, which expired on December 24, 2005.

49. By 2008, sales of Provigil had exceeded $800 million and accounted for over 46% of Cephalon's total sales. This rapid growth led to a federal and state governmental investigation into whether Cephalon was marketing Provigil for "off-label" uses—those other than approved by the FDA. Cephalon eventually entered into a $425 million plea agreement to settle all off-label marketing claims.

50. But for Defendants' wrongful and exclusionary conduct, described herein, each of the Generic Defendants would have obtained final FDA approval. Further, shortly after the expiration of Provigil's Orphan Drug exclusivity on December 24, 2005, each would have begun selling its generic version of Provigil at prices significantly below the price of brand-name Provigil.

A. Cephalon's Provigil Patent

51. The compound known as modafinil, an acetamide derivative, has been known since the late 1980s, as has its neuropsychopharmacological profile.

52. Cephalon, through scientists Peter Grebow, Vincent Corvari, and David Stong, filed United States Application Serial No. 08/319,124 ("the '124 Application") on October 6, 1994. "The '124 Application" is titled "Acetamide Derivative Having Defined Particle Size" with the PTO. The '124 Application could not make broad claims on the compound modafinil, because modafinil was prior art. Rather, the '124 Application claimed certain, narrow uses of specific modafinil formulation, and the certain formulations themselves.

53. The inventors named in the '124 Application assigned their interests to Cephalon and submitted declarations acknowledging their duty to disclose all material information to the PTO and affirming that they were the true and properly named inventors for the '124 Application. This duty of candor extended to all declarants substantively involved in putting forth the '124 Application. The '124 Application issued as United States Patent No. 5,618,845 (the '845 patent) on April 8, 1997.

54. Cephalon filed an NDA for Provigil 100mg and 200mg on December 27, 1996. The NDA indicated the drug would treat narcolepsy. The commercial marketing of Provigil began shortly thereafter.

55. Cephalon determined the '845 patent to be defective on or before April 1, 1990. Consequently, Cephalon filed a reissue application (the "RE '166 Application.") which triggered new duties of candor in those individuals involved in the RE '166 Application process.

B. Generic Defendants File Provigil ANDAs

56. Each Generic Defendant filed an ANDA seeking FDA approval for AB-rated generic versions of Provigil on December 24, 2002, the first day that ANDAs for a generic version of Provigil could be filed under the NCE provisions of Hatch-Waxman.

57. Since each Generic Defendant filed on the same day, they could share 180-day

exclusivity pursuant to Hatch-Waxman. Thus, with FDA approval, all Generic Defendants could simultaneously market generic products during the 180-day exclusivity period. Additionally, the first of these to market its drug would trigger the start of the 180-day exclusivity period for the other Generic Defendants.

58. Mylan filed ANDA No. 76-594 to market generic Provigil in the form of 100mg and 200mg doses of modafinil. Mylan's ANDA contained a Paragraph IV certification that its generic Provigil product would not infringe on Cephalon's rights under RE '516. Cephalon received notice of Mylan's ANDA on or about February 12, 2003.

59. On or about February 20, 2003, Cephalon received notice from Barr regarding its ANDA (No. 76-597) to market 100mg and 200mg doses of generic Provigil. Barr's ANDA included a Paragraph IV certification that its generic version of Profigil would not infringe RE '516.

60. On February 25, 2005, Teva notified Cephalon of its ANDA No. (76-596) to market 100mg and 200mg doses of generic Provigil. Teva's ANDA also included a Paragraph IV certification that the commercial manufacture, use, and/or sale of its generic product would not infringe any valid and enforceable claim of the RE '516 patent.

61. On March 21, 2003, Ranbaxy notified Cephalon that it had filed an ANDA to market generic Provigil in 100mg and 200mg doses, with Paragraph IV certification regarding non-infringement of RE '516.

62. By December 24, 2005, the date that Orphan Drug exclusivity for Provigil expired, each of the Generic Defendants had received the FDA's tentative approval for its generic version of Provigil. Tentative approval meant that the ANDAs were deemed to be safe, effective and bioequivalent to the corresponding brand-name drug by the FDA.

C. Cephalon Files Patent Infringement Suit Against Generic Defendants

63. On March 28, 2003 in the District of New Jersey, Cephalon filed a patent infringement suit against the Generic Defendants alleging infringement of RE '516.

64. During the course of discovery facts were uncovered that seriously undermined Cephalon's claims, including the enforceability of RE '516 and Cephalon's infringement theory.

65. Cephalon's infringement suit had clear problems, including that the modafinil compositions and methods claimed in the Cephalon patents were developed and manufactured by Laboratoire L. Lafon ("Lafon"), not by Cephalon. Cephalon's patent attorneys and the named "inventors" on the patents did not inform the PTO of this information before the '845 patent issued and during the RE '516 patent process.

66. In addition, Lafon sold and delivered modafinil tablets to Cephalon, under a contract signed in January 1993, containing a statement that the active ingredients were the same as the composition claims made in Cephalon's patents. No one from Cephalon—neither patent attorneys nor named "inventors" —informed the PTO of these highly relevant facts, in clear violation of their duty of candor to the PTO in the patent process for both the '845 and RE '516 patents.

67. Cephalon's failure to disclose material and adverse facts in the prosecution of their patents became further apparent after discovery revealed intentional misrepresentation by Cephalon regarding material facts known to Cephalon about Lafon's clinical trials.

68. Lafon's modafinil tablets administered half of the daily dose of modafinil in each of two daily doses, whereas the domestic clinical trial conducted by Cephalon administered the entire daily dose in a single dose. During patent prosecution, Cephalon relied upon the existence of purported differences in adverse effects in the domestic and foreign trials in support of

patentability, failing to disclose this vital protocol change. The protocol change could have explained the difference in adverse effects relied on by Cephalon to support its patent, but during the prosecution of the RE '516 patent, Cephalon agents directly violated their duty of candor to disclose these facts, and again willfully refused any such disclosure.

69. Cephalon's misrepresentations to the PTO continued regarding their clinical trials. Cephalon represented that adverse effects observed at 800mg were wholly unexpected when, in fact, Lafon had informed Cephalon in 1993 of adverse effects in 600mg dosage. This was known to named inventor Peter Grebow, yet the patent specification reports that no clinically significant adverse events occurred in Lafon's trials. In reality, many adverse events occurred in those trials, and discovery proved that such was known to Cephalon and Peter Grebow during the patent process *e.g.,* Grebow sent a copy of Lafon's "serious adverse event" information to a colleague.

70. The extent of Cephalon's intentional concealment included domestic clinical trials described in the Cephalon patents that occurred prior to both the critical date and the alleged conception date. The subjects of the first United States clinical trial were members of the public, and they were under no obligation of confidentiality to Cephalon or the clinical investigators. The non-confidential, public clinical trial was material to patentability.

71. Further, the extent of Cephalon's intentional concealment included that the dog plasma level data discussed in the Cephalon patents demonstrated that the claimed small particle modafinil compositions result in higher peak plasma levels than the large particle modafinil compositions of the prior art. Cephalon knew that the test results were not statistically significant. Indeed, the contrary was true, and Cephalon's report to the FDA, DM-93-014, contradicts its report to the PTO. While the '845 patent was still pending and before the RE '516 patent was filed, as early as November 8, 1996, Cephalon's report concluded that there was no

statistically significant difference in the peak plasma levels as a function of modafinil particle size. Cephalon withheld the FDA report during prosecution of the '845 patent in violation of its duty of candor.

72. Cephalon's intentional concealment also included that it failed to disclose and willfully withheld that Lafon had already considered the importance of maintaining particle size controls over modafinil drug product prior to Cephalon's alleged invention. Specifically, that modafinil bioavailability differences may be caused by the particle size distribution, which is material to patentability, and which was willfully withheld from the PTO by Cephalon.

73. Indeed, Lafon provided Cephalon with all the particle size information, including API Lot 003, but the Cephalon patents misleadingly suggest that Cephalon was the first to measure particle size for modafinil, and the first to understand the significance of particle size. Cephalon falsely claimed that one of its inventors discovered that the dissolution rate of modafinil increases with a decrease in particle size, which was discovered by Lafon in 1989 and communicated to Cephalon in 1993.

74. The Generic Defendants alleged in detail the foregoing facts supporting inequitable conduct defenses and counterclaims in their amended answers filed in February 2005.

75. The Generic Defendants filed and fully briefed motions for summary judgment that the RE '516 patents were invalid as a matter of law by November 14, 2005, including arguing that their non-infringement evidence was so clear as to merit a finding under Fed. R. Civ. P. 11 that the generic products did not infringe on RE '516 as a matter of law.

76. Beginning in December 2005, before the court ruled on the summary judgment motions, Cephalon settled its patent infringement suit with the Generic Defendant which resulted

in dismissals with prejudice.

D. Cephalon's Unlawful Anticompetitive Scheme to Maintain Its Provigil Monopoly

77. The patent infringement suits against the Generic Defendants were unlikely to prevent generic modafinil from coming to market.

78. First, the automatic 30-month stay resulting from Cephalon's patent suits expired in September 2005. Second, Cephalon's claims based on the RE '516 patent seemed unlikely to succeed on the merits, a legal threshold necessary for enjoining the generic competitors from introducing their modafinil products after the 30-month stays had elapsed. Further, the Generic Defendants had all received tentative approval for their generic Provigil ANDAs by January 2005.

79. Cephalon knew its Orphan Drug Exclusivity was set to expire on December 24, 2005, and that if it did nothing generic Provigil would come onto the market, which would result in a rapid destruction of branded Provigil sales as consumers switched to the much cheaper generic version.

80. Cephalon management seemed resigned to the inevitability of imminent generic competition, going as far to inform their investors in November 2005 that the release of generic modafinil in 2006 would result in lower Provigil sales in 2006.

81. Accordingly, Cephalon management prepared for generic Provigil's arrival by reducing promotional spending on Provigil in late 2005. Such behavior usually indicates the expectation of competition in the near future because the reduction can directly lead to reduced sales and profits for the manufacturer.

82. Generic Defendants made preparations to launch their generic modafinil products in 2006.

83. Cephalon also sought FDA approval for Nuvigil, a new formulation of modafinil to combat generic Provigil's arrival by converting Provigil users to another brand-name drug to mitigate the losses from generic modafinil competition. While longer lasting in effect than Provigil, industry analysis did not believe that Nuvigil represented a significant or meaningful improvement over Provigil.

84. On information and belief, in late 2005, Cephalon began negotiating settlement of the patent infringement suit with some of the Generic Defendants. Cephalon targeted pushing back generic entry until three years before expiration of patent exclusivity for Nuvigil. This would not only allow additional time to sell brand-name Provigil at pre-generic market prices, but also to build a consumer base for Nuvigil.

85. The only purpose of these "settlements" was to delay generic competition for Provigil for as long as possible. To achieve this purpose, Cephalon would have to keep all Generic Defendants' modafinil products from entering the market, resulting in the majority of Provigil consumers' switching to the substantially less expensive generic product.

86. As a *quid pro quo* for these unlawful agreements, Cephalon provided Generic Defendants substantial payments in the form of 13 purportedly independent business transactions totaling over $200 million, including intellectual property licenses, supply agreements, and co-development deals (collectively "side-term inducements.")

87. The side-term inducements Cephalon provided to the Generic Defendants were not independent business deals, but rather the price paid for entering into the unlawful settlement agreements to delay generic entry. The side-term inducements were entered into: (i) contemporaneously with the settlements and are often referenced in the same documents; (ii) without substantive discussions between Cephalon Generic Defendants about any such payments

or inducements prior to the settlements being reached; and (iii) the intellectual property licenses and supply agreements confer no benefit to Cephalon other than delaying generic competition.

88. Generic Defendants also received an "acceleration clause" allowing for immediate entry by settling Generic Defendants if another generic manufacturer entered the modafinil market. This clause was calculated to induce the remaining Generic Defendants to settle rather than to continue to litigate and/or enter the modafinil market at risk of infringement.

89. Cephalon's unlawful agreements with Generic Defendants had the sole purpose of maintaining Cephalon's modafinil monopoly.

i. The Teva Settlement

90. Cephalon settled its patent suit against Teva on December 8, 2005, under terms that required Teva to keep its generic Provigil off the market until 2011 or 2012, unless another generic entered the market before then.

91. Teva was to receive up to $125 million in Provigil royalties. These payments were nominally in exchange for a license to Teva's modafinil patent rights, and for an agreement for Teva to supply Cephalon with the provigil active pharmaceutical ingredient ("API").

92. Cephalon had no need for Teva's patent rights, as it already had all it needed to sell Provigil and follow-on products such as Nuvigil—and was already selling modafinil in the U.S. and Europe for at least six years prior. This license agreement operated only as a pretext for Teva not to enter the market with its generic Provigil product.

93. In addition, Cephalon already had supply agreements in place to obtain sufficient modafinil to meet market demand at prices cheaper than under the Teva supply agreement. These payments were solely in exchange for keeping generic Provigil off the market for up to six years.

94. Furthermore, as it was apparent that Cephalon's infringement suit would not

succeed in keeping Teva's generic off the market, the only economic motivation for Teva's agreeing to keep generic Provigil off the market were the payments from Cephalon in the settlement of its infringement suit.

95. Lastly, at the time of the settlement, Teva knew the right to market a generic version of Provigil after 2011 would be worth very little—or nothing at all—as Cephalon would have converted the market from Provigil to Nuvigil by 2011. Teva's generic Provigil was not AB-rated with Nuvigil and, therefore, could not be substituted when filling a Nuvigil prescription.

96. Thus, the settlement agreement with Teva was designed to compensate Teva in exchange for Cephalon's opportunity to obtain FDA approval of Nuvigil to convert the market from Provigil to Nuvigil.

97. Until the settlement with Teva (and the other Generic Defendants), Cephalon was planning to launch Nuvigil in early 2006. After the settlements, however, Cephalon announced that it would delay marketing Nuvigil until at least 2010—one year before generic Provigil would enter the market.

ii. The Ranbaxy Settlement

98. Cephalon reached a similar unlawful anticompetitive settlement with Ranbaxy on December 22, 2005, with Ranbaxy agreeing to keep its generic Provigil product off the market until 2011 or 2012 unless another generic came on the market before then.

99. Ranbaxy required valuable compensation in exchange for marketing generic Provigil. Specifically, Ranbaxy's chief negotiator sought to extract $20 to $30 million in exchange for the settlement, and said he would not recommend settlement without such compensation "because the economics of the situation would be quite different."

100. Cephalon paid Ranbaxy's demands, in part, in the form of a supply agreement. Ranbaxy provided the Provigil API to Cephalon at a substantial mark-up from its supplier in India. These prices were substantially higher than those being charged by Cephalon's existing supplier.

101. Cephalon also agreed to pay up to $5 million to license Ranbaxy's modafinil patent applications, even though Cephalon had no need for such licenses in order to market or sell Provigil and Nuvigil.

102. The supply agreement and license agreement amounted to payments that caused Ranbaxy to agree to keep its generic Provigil off the market until 2011 or 2012.

iii. The Mylan Settlement

103. On January 9, 2006, Cephalon reached an unlawful anticompetitive agreement with Mylan to settle its patent infringement suit and keep Mylan's generic Provigil product off the market until 2011 or 2012.

104. Prior to this settlement, Mylan issued a written statement predicting 100% probability of bringing generic Provigil onto the market by June 2006.

105. Contemporaneous with the settlement, Cephalon entered into product development agreements with Mylan, resulting in at least $45 million in benefit to Mylan. Cephalon had expressed no interest in the technology that was the subject of the product development deals before its settlement with Mylan.

106. The value paid to Mylan through these product development deals caused Mylan to keep its generic Provigil product off the market until 2011 or 2012.

iv. The Barr Settlement

107. Cephalon also settled with Barr and Barr's partner Chemagis, Ltd. (collectively

with Chemagis affiliates "Chemagis") on February 1, 2006. As with the settlements involving the other Generic Defendants, Barr was required to refrain from marketing generic Provigil until 2011 or 2012, unless another generic version of Provigil came onto the market before then. In exchange, Barr required, and Cephalon agreed to: (i) pay $1 million for a license to Barr's patent applications related to modafinil; (ii) purchase modafinil API from Chemagis; and (iii) settle unrelated patent litigation on terms favorable to Barr.

108. Cephalon agreed to pay $4 million to Chemagis for a license to a patent and patent application Chemagis held in conjunction with Barr for generic Provigil. Cephalon had no need for these licenses to sell Provigil or Nuvigil. Cephalon also entered into an agreement with Chemagis to develop drug delivery products. Cephalon agreed to pay $40 million to Chemagis in conjunction with these product development projects.

109. The significant compensation provided to Barr and Chemagis by Cephalon was intended to, and did achieve, a settlement of the patent infringement lawsuit which resulted in Barr and Chemagis keeping generic Provigil off the market until 2011 or 2012.

110. Teva, Ranbaxy, Mylan and Barr agreed to refrain from selling generic Provigil whether or not it infringed on Cephalon's particle size patent, from developing alternate generic version of Provigil, and from developing or marketing generic equivalents to successor products to Provigil like Nuvigil.

111. Without these unlawful agreements to restrict competition for up to six years, all of the Generic Defendants would have been granted approval from the FDA to market generic Provigil, and would have begun selling generic Provigil by January, 2006.

112. Without the unlawful exclusion payments from Cephalon, the Generic Defendants would have had substantial economic incentive to sell generic Provigil as soon as they could in

order to profit from their research and development investments. Each Generic Defendant would have been motivated to come to market quickly, knowing that if one generic did not come to market, another generic would capture its share of the market.

113. Frank Baldino, Jr., Cephalon's CEO, described the reasons behind Cephalon's stock surge after the settlements: "A lot of [Wall Street's support of Cephalon stock] is a result of the patent litigation getting resolved for Provigil. We were able to get six more years of patent protection. That's $4 billion in sales no one expected." *Philadelphia Business Journal*, March 20, 2006.

114. The exclusion payments ensured that consumers would not have access to generic Provigil and the massive savings that would have come with it. Such savings could reasonably be expected to be at least half of the $4 billion in Provigil sales Cephalon made sure those savings never went to consumers. *See Remarks by Jon Leibowitz, Commissioner, Federal Trade Commission, Second Annual In-House Counsel's Forum on Pharmaceutical Antitrust, April 24, 2006.*

115. After settling with the generic defendants and eliminating generic competition, Cephalon announced that it had "reinvigorated" its Provigil marketing campaigns. Cephalon also suspended the launch of its authorized generic and postponed the anticipated launch of Nuvigil.

VI. ANTICOMPETITIVE EFFECT

116. Defendants' conduct, in whole or in part, has enabled Defendants to: (i) prevent or delay the entry of less expensive generic versions of Provigil in the United States; and (ii) fix, raise, maintain, or stabilize the price of Provigil and its generic equivalent, modafinil.

117. But for Defendants' illegal conduct, generic manufacturers would have entered the market unimpeded and competed on the merits. Generic competitors would have likely

competed as early as December 24, 2005.

118. Defendants' conduct unlawfully delayed and diminished the savings that purchasers of Provigil and its generic equivalent, modafinil would have gained from unimpaired generic competition.

119. Defendants' conduct, in whole or in part, harmed Plaintiff by depriving it of, *inter alia*: (i) a marketplace in which manufacturers and distributors of generic drugs make their decisions about challenging patents and entering markets free from the influence of unlawful payments; and (ii) the most cost efficient means of distribution.

120. Contrary to the purpose of the Hatch-Waxman Act, the anticompetitive conduct enabled Defendants to, *inter alia:* (i) delay the entry of less expensive generic versions Provigil in the United States; (ii) fix, raise, maintain, or stabilize the price of Provigil and its generic equivalent, modafinil; and (iii) permit to maintain a monopoly in the United States market for Provigil and its generic equivalent, modafinil.

121. As a direct and proximate result of Defendants' unlawful conduct, Plaintiff has sustained substantial losses and damage to its business and property in the form of overcharges it paid for Provigil and its generic equivalent, modafinil, the exact amount of which will be proven at trial.

VII. EFFECTS ON INTERSTATE AND INTRASTE COMMERCE

122. At all material times, Cephalon and Teva, who acquired Cephalon in 2011, manufactured, marketed, distributed, and sold substantial amounts of Provigil in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

123. At all material times, Defendants transmitted funds, contracts, invoices, and other forms of business communications and transactions, in a continuous and uninterrupted flow of

commerce across state and national lines in connection with the sale of Provigil and its generic equivalent.

124. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mails and interstate and international telephone lines, and means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and continue to substantially affect) interstate commerce.

125. Defendants' anticompetitive conduct had substantial intrastate effects in that, *infra*, retailers within each state were foreclosed from offering substantially cheaper generic Provigil. The complete foreclosure of generic Provigil directly impacted and disrupted commerce for Plaintiff within Rhode Island by forcing it to buy the branded product at the higher price.

VIII. MARKET POWER AND MARKET DEFINITION

126. At all relevant times, Cephalon (Teva) had market power (*i.e.*, monopoly power) with respect to Provigil and and its generic equivalents because it had the power to maintain the price of Provigil at supra-competitive levels without losing so many sales as to make the supra-competitive price unprofitable. At all relevant times, a small, but significant, non-transitory price increase above the competitive level for Provigil by Cephalon would not have caused a loss of sales sufficient to make the price increase unprofitable.

127. At all relevant times, at competitive price levels Provigil did not exhibit significant, positive cross-elasticity of demand regarding price with any product other than AB-rated generic versions of Provigil. Other medicines not AB-rated to Provigil, which cannot be automatically substituted for Provigil by pharmacists, do not exhibit substantial cross-price elasticity of demand regarding Provigil, and thus are not economic substitutes for, nor reasonably interchangeable with, Provigil.

128. The pharmacological profile of modafinil differs substantially from other psychostimulants such as amphetamines and methylphenidate, which are not reasonably exchangeable with or AB-rated to Provigil.

129. Cephalon needed to control only Provigil and its AB-rated generic equivalents, and no other products, in order to profitably maintain the price of Provigil at supra-competitive levels. Only the market entry of a competing, AB-rated generic version of Provigil would have rendered Cephalon unable to profitably maintain supra-competitive prices for Provigil.

130. At all relevant times, Cephalon sold Provigil at prices well over its marginal costs and its competitive price, and enjoyed the resulting high profit margins and corresponding financial benefits—to the financial detriment of Plaintiff.

131. Cephalon had and exercised the power to exclude and restrict competition to Provigil and its AB-rated bioequivalents.

132. Cephalon, at all relevant times, enjoyed high barriers to entry regarding competition in the relevant product market due to patent and other regulatory protections, and the high cost of entry and expansion.

133. To the extent that the law requires Plaintiff to prove monopoly power circumstantially by first defining a relevant product market, Plaintiff alleges that the relevant market is all modafinil products *i.e.*, Provigil (in all its forms and dosage strengths) and AB-rated bioequivalent modafinil products.

134. The relevant geographic market is the United States and its territories.

135. Prior to generic entry in 2012, Cephalon (Teva) held 100% market share in the relevant market. Following market entry by generic manufacturers and much less expensive generic versions of Provigil, Cephalon's market share for modafinil products declined

dramatically in a short period of time.

IX. MARKET EFFECTS

136. But for the anticompetitive conduct alleged above, generic competition for modafinil would have begun as early as June 1, 2006.

137. Defendants' anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Provigil from generic competition. Defendants' unlawful actions allowed Cephalon (Teva) to maintain a monopoly and exclude competition in the market for Provigil and its generic equivalents, and to maintain supra-competitive prices for Provigil, to the detriment of Plaintiff. Defendants' anticompetitive conduct delayed and impaired generic competition and unlawfully enabled Cephalon to sell Provigil without timely generic competition.

138. Typically, generic drugs are initially priced significantly below the corresponding branded drug to which they are AB-rated. As a result, upon generic entry, consumers typically substitute generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a branded drug predictably plunge even further due to competition among the generic manufacturers and, correspondingly, the branded drug loses even more of its market share. This price competition enables purchasers to: (i) purchase generic versions of a drug at substantially lower prices; and (ii) purchase the branded drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition which, in turn causes purchasers to experience substantial increases in costs.

139. But for Defendants' anticompetitive conduct, Plaintiff would have paid less by: (i) substituting purchases of less-expensive AB-rated generic Provigil for their purchases of more-

expensive branded Provigil; (ii) receiving discounts on their remaining branded Provigil purchases; and/or (iii) purchasing generic Provigil at lower prices sooner.

140. Due to Defendants' anticompetitive conduct, other generic manufacturers were discouraged from and/or delayed in: (i) developing and marketing a generic version of Provigil; and/or (ii) challenging the validity or infringement of Cephalon's patents in court.

141. During the relevant time period, Plaintiff purchased substantial amounts of Provigil and generic Provigil. As a direct and proximate result of Defendants' illegal conduct, Plaintiff was compelled to pay, and did pay, artificially inflated prices for Provigil and its generic equivalent. Plaintiff paid prices that were substantially greater than the prices they otherwise would have paid absent Defendants' illegal conduct because it: (i) was deprived of the opportunity to purchase lower-priced generic Provigil instead of expensive branded Provigil; and (ii) paid artificially inflated prices for Provigil and its generic equivalent.

142. Defendants' anticompetitive conduct has substantial intrastate effects in that, *infra*, retailers within each state are foreclosed from offering less expensive generic Provigil inside each respective state. The foreclosure of these generic drugs directly impacts and disrupts commerce for Plaintiff by forcing them to buy the branded product at the higher price.

143. As a direct and proximate result of Defendants' unlawful anticompetitive scheme and wrongful conduct, Plaintiff has sustained substantial losses and damage to its business and property in the form of overcharges it paid for Provigil and its generic equivalent, the exact amount of which will be proven at trial.

144. Defendants' unlawful conduct deprived Plaintiff of the benefits of free and unrestrained competition that the antitrust laws were designed to ensure.

X. ANTITRUST IMPACT

145. During the relevant period, Plaintiff purchased substantial amounts of branded Provigil indirectly from Defendants. As a result of Defendants' illegal conduct, Plaintiff was compelled to pay, and did pay, artificially inflated prices for Provigil and generic Provigil. Those prices were substantially greater than those that Plaintiff would have paid absent the illegal conduct alleged herein.

146. As a consequence, Plaintiff has sustained substantial loss and damage to its business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

147. General economic theory recognizes that any overcharge at a higher level of distribution in the chain of distribution for Provigil results in higher prices at every level below. *See* HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY, THE LAW OF COMPETITION AND ITS PRACTICE 624 (1994). Professor Herbert Hovenkamp goes on to state that "[e]very person at every stage in the chain will be poorer as a result of the monopoly price at the top." He also acknowledges that "[t]heoretically, one can calculate the percentage of any overcharge that a firm at one distribution level will pass on to those at the next level."

148. Defendants' anticompetitive conduct enabled them to charge consumers indirectly and third-party payors prices in excess of what Defendants otherwise would have been able to charge absent Defendants' anticompetitive conduct.

149. The prices were inflated as a direct and foreseeable result of Defendants' anticompetitive conduct.

150. The inflated prices the Plaintiff paid are traceable to, and the foreseeable result of, the overcharges by Defendants.

XI. CLAIMS FOR RELIEF

COUNT I

CONSPIRACY AND COMBINATION IN RESTRAINT OF TRADE UNDER STATE LAW
(Against All Defendants)

151. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

152. The unlawful reverse payment or exclusion agreements between Cephalon (Teva) and each Generic Defendant regarding Provigil involves: (i) a payment from Cephalon to each Generic Defendant; and (ii) an agreement by each Generic Defendant to delay marketing its generic Provigil. The payments from Cephalon to each Generic Defendant under each respective agreement was the *quid pro quo* for each Generic Defendant's agreement to delay marketing its generic version of Provigil. Absent the payments, no Generic Defendant would have agreed to delay marketing its generic versions of Provigil and all would have entered the market sooner than it did.

153. The purpose and effect of the payments flowing from Cephalon to each Generic Defendant under the agreement was to delay generic competition to Provigil, and there is and was no legitimate, non-pretextual, procompetitive business justification for the payments that outweighs their harmful effect. Even if there were some such conceivable justification, the payments were not necessary to achieve such a purpose.

154. The purpose and effect of the unlawful reverse payment or exclusion agreements between Cephalon and each Generic Defendant was to allocate 100% of the market for Provigil and its generic equivalents in the United States to Cephalon, delay the sale of generic Provigil products, and fix, raise, maintain, or stabilize the price at which Plaintiff would pay for Provigil.

155. The unlawful reverse payment or exclusion agreements harmed competition.

156. As a direct and proximate result of Cephalon and each Generic Defendants' unlawful restraint of trade, Plaintiff paid artificially inflated prices for Provigil and its generic equivalents as described herein, and was harmed as a result.

157. By engaging in the foregoing conduct, Cephalon and each Generic Defendant violated the following state laws:

a. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Cal. Bus. Code §§ 16700, *et seq.,* and Code §§ 17200, *et seq.,* with respect to purchases of Provigil and/or its generic equivalent, modafinil, in California by Plaintiff.

b. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Fla. Stat. §§ 501. Part II, *et seq.,* with respect to purchases of Provigil and/or its generic equivalent, modafinil, in Florida by Plaintiff, and this conduct constitutes a predicate act under the Florida Deceptive Practices Act.

c. Defendants have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of Provigil and/or its generic equivalent, modafinil, in Illinois by Plaintiff.

d. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of Me. Rev. Stat. Ann. 10, § 1101, *et seq.,* with respect to purchases of Provigil and/or its generic equivalent, modafinil, in Maine by Plaintiff.

e. Defendant have intentionally and wrongfully engaged in a combination and conspiracy in restraint of trade in violation of Mass. Ann. Laws ch. 93, *et seq*., with respect to purchases of Provigil and/or its generic equivalent, modafinil, in Massachusetts by Plaintiiff, paying substantially higher prices for Provigil and/or its generic equivalent, modafinil, in actions and transactions occurring substantially within Massachusetts.

f. Defendants have intentionally and wrongfully engaged in a contract, combination or conspiracy in restraint of trade in violation of R.I. Gen. Laws §§ 6-36-5, *et seq*., with respect to

purchases of Provigil and/or its generic equivalent, modafinil, in Rhode Island by Plaintiff.

158. Plaintiff has been injured in its business or property by reason of Cephalon and each Generic Defendants' antitrust violations, in that Plaintiff: (i) was denied the opportunity to more timely purchase lower-priced generic Provigil; and (ii) paid higher prices for branded Provigil than they would have paid in the absence of the unlawful conduct. These injuries are of the type the laws of the above states were designed to prevent, and flow from that which makes the conduct unlawful.

159. Plaintiff seeks damages and multiple damages as permitted by law for its injuries.

COUNT II

MONOPOLIZATION UNDER STATE LAW
(Against Defendants Cephalon and Teva)

160. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

161. At all relevant times, Cephalon (Teva) possessed monopoly power in the modafinil market.

162. As described herein, Cephalon entered into unlawful agreements with the Generic Defendants to settle patent infringement suits as part of an overall anticompetitive scheme to unlawfully maintain its monopoly power in the market for modafinil.

163. Had manufacturers of generic Provigil entered the market and lawfully competed in a timely fashion, Plaintiff would have substituted lower-priced generic Provigil for some or all of their modafinil needs.

164. As described herein, Cephalon entered into anticompetitive agreements with each Generic Defendants to delay generic entry.

165. The goal, purpose, and effect of Cephalon's unlawful conduct was to maintain and extend its monopoly power in the modafinil market. Cephalon's unlawful anticompetitive scheme to prevent, delay, and/or minimize the success of the introduction into the United States marketplace of any generic versions of Provigil enabled Cephalon to continue charging supracompetitive prices for Provigil without a substantial loss of sales.

166. If manufacturers of generic versions of Provigil had been able to enter the market and fairly compete with Cephalon in a full and timely fashion, Plaintiff would have substituted lower-priced generic versions of Provigil for some or all of their modafinil requirements, and/or would have received lower prices on some or all of their remaining branded modafinil purchases, at earlier periods of time and in far greater quantities.

167. Plaintiff indirectly purchased substantial amounts of Provigil from Cephalon during the relevant time period.

168. As a result of Cephalon's (Teva) unlawful conduct, Plaintiff was forced to pay, and did pay, more than they would have paid for Provigil and/or its generic equivalent, modafinil.

169. By engaging in the foregoing unlawful conduct, Cephalon (Teva) has violated the following state antitrust laws:

a. Teva has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq.*, with respect to purchases of Provigil and/or its generic equivalent, modafinil, in California by Plaintiff.

b. Teva has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Fla. Stat. §§ 542.19, *et seq.* and 501.201, et seq., with respect to purchases of Provigil and/or its generic equivalent, modafinil in Florida by Plaintiff.

c. Teva has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of 740 Ill. Comp. Stat. § 10/3(3),

with respect to purchases of Provigil and/or its generic equivalent, modafinil in Illinois by Plaintiff.

d. Teva has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Me. Rev. Stat. Ann. tit.10, §§ 1102, *et seq*., with respect to purchases of Provigil and/or its generic equivalent, modafinil in Maine by Plaintiff.

e. Teva has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of Mass. Ann. Laws ch. 93A, *et seq*., with respect to purchases of Provigil and/or its generic equivalent, modafinil in Massachusetts by Plaintiff.

f. Teva has intentionally and unlawfully maintained its monopoly power in the relevant market in violation of R.I. Gen. Laws §§ 6-36-1, *et seq*., with respect to purchases of Provigil and/or its generic equivalent, modafinil in Rhode Island by Plaintiff.

170. Plaintiff has been injured in its business or property as a direct and proximate result of Defendants' anticompetitive conduct. Their injuries consist of: (i) being denied the opportunity to purchase lower-priced generic Provigil; and (ii) being forced to purchase more expensive branded Provigil. These injuries are of the type the above antitrust laws were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

171. Plaintiff seeks damages as permitted by law for the injuries they suffered as a result of the Defendants' anticompetitive conduct. Defendants are jointly and severally liable for all damages suffered by Plaintiff.

COUNT III

CONSUMER PROTECTION AND UNFAIR AND DECEPTIVE TRADE PRACTICES UNDER STATE LAW

(Against all Defendants)

172. Plaintiff hereby incorporates each preceding and succeeding paragraph as though fully set forth herein.

173. As a direct and proximate result of Defendants' unfair competition and unfair or

unconscionable acts or practices in violation of the state consumer protection statutes listed below, Plaintiff was deprived of the opportunity to purchase a generic version of Provigil and forced to pay higher prices for Provigil.

174. By engaging in the foregoing conduct, Defendants have violated the following state unfair trade practices and consumer fraud laws:

a. Defendants have engaged in unfair competition or unfair acts or practices in violation of Cal. Bus. & Prof. Code §§ 17200, *et seq*.

b. Defendants have engaged in unfair competition or unfair acts or practices in violation of Fla. Stat. §§ 501.201, *et seq*.

c. Defendants have engaged in unfair competition or unfair acts or practices in violation of 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq*.

d. Defendants have engaged in unfair competition or unfair acts or practices in violation of Me. Rev. Stat. tit. 5 §§ 207, *et seq*.

e. Defendants have engaged in unfair competition or unfair acts or practices in violation of Mass. Gen. Laws ch. 93A, *et seq*.

f. Defendants have engaged in unfair competition or unfair acts or practices in violation of R.I. Gen. Laws §§ 6-13.1-1, *et seq*.

175. Plaintiff has been injured in its business and property by reason of Defendants' anticompetitive, unfair or unconscionable acts alleged herein. Their injury consists of being forced to purchase a more expensive branded Provigil product or the generic version at a higher price than it otherwise would have been had competition on the merits occurred earlier. This injury is of the type the state consumer protection statutes were designed to prevent and directly results from Defendants' unlawful conduct.

COUNT IV

UNJUST ENRICHMENT
(Against all Defendants)

176. In the alternative, Defendants have benefited from their sales of Provigil or generic Provigil.

177. Defendants' financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Provigil and generic Provigil by Plaintiff.

178. Plaintiff has conferred upon Defendants an economic benefit in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff.

179. The economic benefit of overcharges and unlawful monopoly profits derived by Defendants through charging supra-competitive and artificially inflated prices for Provigil or generic Provigil is a direct and proximate result of Defendants' unlawful practices.

180. The financial benefits derived by Defendants rightfully belong to Plaintiff, as Plaintiff paid anticompetitive and monopolistic prices, inuring to the benefit of Defendants.

181. It would be inequitable for the Defendants to be permitted to retain any of the overcharges for Provigil or generic Provigil derived from Defendants' unfair and unconscionable methods, acts, and trade practices alleged herein.

182. Defendant should be compelled to disgorge for the benefit of Plaintiff all unlawful or inequitable proceeds received by them.

183. Plaintiff has no adequate remedy at law.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter an Order that:

A. Enters judgment against Defendants in favor of Plaintiff;

B. Declares the Defendants' conduct to be in violation of the antitrust and/or deceptive practice statutes;

C. Grants Plaintiff equitable relief in the nature of declaratory relief, injunction, disgorgement, restitution, and the creation of a construction trust to remedy Defendants' unjust enrichment;

D. Grants Plaintiff damages as permitted by law, including disgorgement;

E. Awards the Plaintiff damages (*i.e.*, three times overcharges) in an amount to be determined at trial;

F. Awards Plaintiff their costs of suit, including reasonable attorneys' fees as provided by law; and

G. Grants such other further relief as is necessary to correct for the anticompetitive market effects, caused by Defendants' unlawful conduct, as the Court deems just.

XIII. JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff demands a trial by jury on all issues so triable.

Dated: June 29, 2015

By: */s/ Vincent L. Greene, IV*

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